

Remarks

This communication is in response to the Office Action mailed December 14, 2001, in the above identified application, which application is related to antibacterial diapers and wet wipes for the cleansing of infants, said diapers and wipes comprising hop acid derivatives, specifically tetrahydroiso-alpha acid and hexahydro-beta acid. As noted in the specification, these compounds are effective to inhibit the growth of gram-positive bacteria, and specifically *Staphylococcus aureus*, as well as TSST-1, toxic shock syndrome toxin-1.

In the Office Action, all pending Claims were rejected by the Examiner, on the basis of 35 U.S.C. 103(a) as unpatentable over Nutter *et al.* (US 6,313,178), by itself, or under 35 U.S.C. 103(a) as unpatentable over Nutter *et al.* in combination with any one of Tramontana (US 6,284,261), Carraher, Jr. *et al.* (US 5,840,760), or Pierce *et al.* (US 6,262,038). The Examiner cites Nutter *et al.* as teaching a composition for inhibiting *Staphylococcus aureus* growth by contact with hexhydrolupone or tetrahydroisohumulone, in an aqueous base comprising water, alcohol, propylene glycol or glycerin. As noted by the Examiner, the patent does not teach the inclusion of alpha and beta acids and their derivatives in diapers or wipes. The Examiner, however, indicates that such inclusion would be obvious since the inclusion of antimicrobial agents in diapers and wipes is well known in the art. The Examiner further cites Tramontana as teaching diapers and wipes comprising antimicrobial agents that inhibit *Staphylococcus aureus* and an alcohol; Carraher, Jr., *et al.* as teaching control of *Staphylococcus aureus* by impregnation of an antimicrobial agent into a diaper; and Pierce *et al.* as teaching baby wipes effective against *Staphylococcus aureus* and comprising alpha hydroxy acids and a liquid such as alcohol, glycerin or propylene glycol. The Examiner concludes that it would have been obvious to one of ordinary skill in the art to include alpha and beta acid derivatives in diapers or wipes with an expectation of controlling infection.

Applicants, by the present amendment, have herewith amended the Claims of the present application so as to overcome the rejections as applied by the Examiner. Specifically, the Claims have been amended to specify that the invention relates to inhibition of microbial growth in liquids in contact with an infant, that the diaper is dry, and that the antimicrobial employed is effective against toxic shock syndrome toxin-1. The "Version of Amendment with Markings to Show Changes Made" submitted hereinafter reflects this amendment of the Claims.

With respect to the references applied by the Examiner, Applicants offer the following comments. First, the Nutter *et al.* patent is specific to treatment of cancer, and as indicated by the Examiner, totally fails to teach the use of hydrogenated lupulones or derivatives in the context of the present invention. While the Examiner indicates that the reference teaches topical application of such compounds, it must be noted that such usage is indicated as being for the specified purpose of killing cancer cells or inhibiting their growth through the use of certain beta acids, and that the use thereof for this purpose is dependent upon the delivery system being capable of penetrating each layer of skin. In contrast, the present invention is directed to the inhibiting of bacterial growth upon the surface of the skin or on a skin wound, thus not dependent upon transdermal penetration. Applicants submit that it would be neither taught nor obvious to one skilled in the art that application of these materials to a surface in the manner claimed would be beneficial, especially for inhibition of toxic shock syndrome.

With respect to the Tramontana reference, it is noted that this patent is specific to disposable absorbent articles containing an additive to control odors associated with bodily fluids. The patent is specifically directed to the use of essential oils, defined at column 2, lines 40-41 as being highly concentrated, volatile liquids originating from a single botanical source. Further, the patentee states that the article contains "one or more essential oils in an amount effective to provide two functions: emit a pleasant aroma, and inhibit microbial growth." Thus, the patentee is dependent upon a masking of the objectionable odor, as well as upon an antimicrobial effect. Moreover, the reference makes no reference to combating toxic shock syndrome. Applicants submit

that one of ordinary skill in the art ⁽³⁾ would have no reason to combine the teachings of this reference, relating to disposable articles for odor control, with those of Nutter *et al.*, relating to an anti-cancer drug. Further, even were one to combine the teachings of the two references, one would not be led to use an antimicrobial compound selected from the group consisting of tetrahydroiso-alpha acids, hexahydro-beta acids, and mixtures thereof, for the purpose of combating toxic shock syndrome.

The Carraher, J. *et al.* patent teaches the use of modified tin-containing polymers to control methicillin resistant *Staphylococcus aureus*, by impregnation of said ⁽¹⁾ compounds into various articles to control and prevent outbreaks of *Staphylococcus aureus* thereon. While this patent does teach that such compounds may be incorporated into a diaper, the compounds utilized are a far cry from the naturally occurring derivative of a natural source which is used in the present invention. Again, one of ordinary skill in the art would not be led to combine the teachings of Nutter *et al.*, which relate to anticancer agents, with the teachings of Carraher, Jr. *et al.*, which are related to the use of organotin polymeric compounds for antimicrobial purposes, much less for inhibiting toxic shock syndrome.

It is believed that the teachings of Pierce *et al.*, relative to a germicidal wash for fruit and vegetables, fail to overcome the failings of the other references relied upon by the Examiner. First, it must be noted that while the composition of the patent is said to be 100% effective against *Escherichia coli*, *Salmonella typhi*, and *Shigella dysenteriae*, within 30 seconds of application, there is no specific indication that the composition may be effective against toxic shock syndrome toxin-1, and thus against toxic shock syndrome. Accordingly, one of ordinary skill in the art, familiar with the teachings of Nutter *et al.* and Pierce *et al.* would not be led to the present invention, since neither indicates a utilization or use of an antimicrobial compound selected from the group consisting of tetrahydroiso-alpha acids, hexahydro-beta acids, and mixtures thereof, for the purpose of combating toxic shock syndrome.

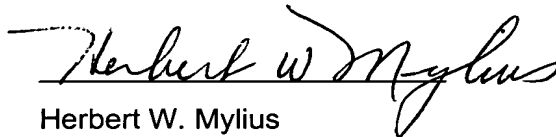
It is further submitted that the remaining references made of record by the Examiner as being pertinent does not overcome the deficiencies of the above-discussed references.

Accordingly, it is submitted that the references fail, either individually, or in combination, to teach, make obvious, or suggest the application of tetrahydroiso-alpha acids and hexahydro-beta acids to combat *Staphylococcus aureus* and toxic shock syndrome toxin-1, as set forth by the Claims of the present application. Therefore, reconsideration of the Claims of this application, as amended, is requested, and a prompt notification of the allowability thereof is solicited.

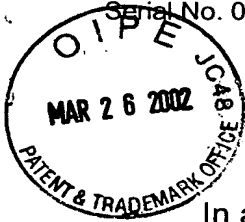
Respectfully submitted,

On behalf of Applicants Barney *et al.*

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Herbert W. Mylius
Quarles & Brady, LLP
411 East Wisconsin Avenue
Milwaukee, WI 53202
Reg. No. 24,578
(414) 277-5477



Version of Amendment with Markings to Show Changes Made

In accordance with 37 CFR 1.121(c)(1)(iii), the following constitutes a marked-up version of the Claims amended in the present AMENDMENT, indicating the changes made in the Claims as rewritten.

1 (Amended) A method for inhibiting the growth of *Staphylococcus aureus* and toxic shock syndrome toxin-1 in liquids in contact with [on] infants, said method comprising the step of:

diapering the infant with a dry diaper comprising an effective amount of an antimicrobial compound selected from the group consisting of tetrahydroiso-alpha acids, hexahydro-beta acids, and mixtures thereof.

2. The method of claim 1, wherein said diaper is a disposable diaper, and said method inhibits toxic stress syndrome.

3 (Amended). The method of claim 2, wherein said compound is applied to the diaper dissolved in a liquid selected from the group consisting of water, alcohols, propylene glycol, glycerin, polyglycols, and mixtures thereof, and said diaper is subsequently dried so as to be dry to the touch.

4 (Amended). A dry diaper containing an antimicrobial compound selected from the group consisting of tetrahydroiso-alpha acids, hexahydro-beta acids, and mixtures thereof, said antimicrobial compound being effective against toxic shock syndrome.

6 (Amended): ~~A-cleansing wet wipe comprising an antimicrobial compound~~ effective against toxic shock syndrome toxin-1, said compound selected from the group consisting of tetrahydroiso-alpha acids, hexahydro-beta acids, and mixtures thereof, in

a liquid selected from the group consisting of water, alcohols, propylene glycol, glycerine, polyglycols, and mixtures thereof.